

ACETAMINOPHEN 325MG RS- acetaminophen 325mg tablet

Allegiant Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 325mg

Purpose

Pain reliever/fever reducer

Uses

temporary relief of minor aches and pains associated with:

- headache
- backache
- muscular aches
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- if you are allergic to acetaminophen
- with other products containing acetaminophen (prescription or nonprescription).

If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if user has

liver disease.

Ask a doctor or pharmacist before use if

the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- symptoms do not improve
- pain gets worse or lasts for more than 10 days
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present
- a rare sensitivity reaction occurs
- **You may report side effects to 1-888-952-0050**

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Adults and children 12 years of age and over: Take 2 tablets every 4 to 6 hours.

Do not take more than 10 tablets in 24 hours.

Children 6-11 years of age: Take 1 tablet every 4 to 6 hours as needed.

Do not take more than 5 tablets in 24 hours.

Children under 6 years of age: Do not use this regular strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems.

Other information

- store at room temperature

ACETAMINOPHEN 325MG RS

acetaminophen 325mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (Round Circle)	Size	11mm
Flavor		Imprint Code	AZ;010
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-010-60	1 in 1 CARTON	04/15/2016	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-010-50	1 in 1 CARTON	04/15/2016	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/15/2016	

